UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/553,262	12/20/2005	David Rubinsztein	BJS-620-394	1781

23117 7590 09/28/2011

NIXON & VANDERHYE, PC
901 NORTH GLEBE ROAD, 11TH FLOOR
ARLINGTON, VA 22203

EXAMINER	
ZAREK, PAUL E	

ART UNIT	PAPER NUMBER
1628	

MAIL DATE	DELIVERY MODE
09/28/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/553,262	RUBINSZTEIN ET AL.	
	Examiner	Art Unit	
	PAUL ZAREK	1628	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *41 and 43-93* is/are pending in the application.

5a) Of the above claim(s) *52-93* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *41 and 43-51* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/14/2010 has been entered.

Status of the Claims

2. Claim 41 have been amended by the Applicant in correspondence filed on 04/14/2010. Claims 41 and 43-93 are currently pending. Claims 52-93 remain withdrawn for being drawn to nonelected subject matter. Claims 41 and 43-51 are examined here. This is the first Office Action on the merits of the claim(s) following a request for continued examination.

RESPONSE TO ARGUMENTS

3. Claims 41 and 43-51 were rejected under 35 U.S.C. 112, first paragraph, for not being fully enabled. This rejection is moot in light of Applicants' amendment to Claim 41.

4. Claims 41-47 and 49-51 were rejected under 35 U.S.C. 102(b) as anticipated by Lin, et al. (European Patent Application Publication no. EP 0 778 023 A1, 1997). Applicants traversed this rejection on the grounds that Lin, et al., does not anticipate the instantly claimed invention. Specifically, Applicants contend that Lin, et al., describe treating individuals suffering from

Huntington's disease (HD) but does not disclose administering rapamycin or its analogs to a subject not suffering from HD, or any disease. Applicants also disagree with Examiner's interpretation of the *in vitro* protocol in the prior art. While agreeing that it is not necessarily prevention protocols, Applicants note that this assay examines the effect of rapamycin on glutamate toxicity, not protein aggregation. Respectfully, Examiner does not find Applicants' arguments persuasive in light of Applicants' amendments.

5. Amended Claim 41, from which Claims 43-47 and 49-51 depend, is drawn to a method of delaying the onset of and/or reducing the severity of a protein conformational disorder (PCD) in an individual at risk of suffering from said disorder comprising stimulating autophagy activity in the individual. Stimulating autophagy activity can be achieved through administration of rapamycin or an analog thereof. As written, the claim language "reducing the severity of" is reasonably interpreted as treatment. Thus, treating HD with rapamycin or an analog thereof is encompassed by the instant claims.

6. Lin, et al., explicitly contemplate a method of treating HD comprising administration of rapamycin, or an analog thereof (pg 8, Claim 4). As noted previously, the phrase "wherein said stimulation promotes clearance of said proteins" is considered the intended result of the claimed method and is not a patentably distinguishing feature of the invention (MPEP § 2111.04). Thus, Lin, et al., anticipate all the limitations of the rejected Claims. Therefore, the rejection of Claims 41-47 and 49-51 under 35 U.S.C. 102(b) as anticipated by Lin, et al., is maintained.

7. Applicants may overcome this rejection by clearly stating that the subjects to be treated are not those that have already developed a PCD.

8. Examiner agrees with Applicant that Lin, et al., do not teach or suggest administering rapamycin, or an analog thereof, to a patient who has yet to experience the effects of a PCD, such as HD. The *in vitro* experiment disclosed in this prior art is concerned only with glutamate toxicity and the artisan could not reasonably extrapolate the results of this assay to the prophylactic therapy of HD.

9. Applicants are correct that many PCDs are genetic diseases that are mediated by particular alleles. Thus, not every person is at risk for these genetically based PCDs (i.e. HD and Parkinson's disease). Examiner notes, however, not all PCDs are genetic. See rejection below.

10. Claim 48 was rejected under 35 U.S.C. 103(a) as being unpatentable over Lin, et al. (above) in view of the Applicant's own admission (see below). Applicants traversed this rejection for the reasons outlined above. Applicants have not disagreed with that the rapamycin analogues of Claim 48 were well-known at the time of filing. Respectfully, Examiner does not find Applicants' arguments persuasive for the reasons discussed above. Therefore, the rejection of Claim 48 under 35 U.S.C. 103(a) as being unpatentable over Lin, et al. (above) in view of the applicant's own admission is maintained.

11. Below are listed new grounds of rejection following a request for continued examination. Therefore, this office action is considered **non-final.**

Claim Rejections - 35 USC § 102

12. The text of Title 35, U.S.C. § 102(a) can be found in a prior Office action.

13. Claims 41 and 43-46 are rejected under 35 U.S.C. 102(a) as being anticipated by Cotterell, et al. (Clinical Transplantation, 2002).

14. Claims 41 and 43-46 were described above and previously. As noted above, not all PCDs are genetic in nature. For example, sporadic Creutzfeldt-Jakob disease (sCJD) is a PCD that can be caused by consumption of beef infected with mad cow disease (Mitchell, UPI, 2003). Walker (SciTopics, 2008) teaches that prion disease is a PCD that can be idiopathic, genetic, or infectious in origin. Since some PCDs can be acquired independent of a person's genetic make-up, all persons are at risk of developing such PCDs.

15. Cotterell, et al., teach a method of treating transplant liver rejection by administration of rapamycin (pg 50, col 1, para 2). Although not explicitly stated, each patient was at risk of developing sCJD. Therefore, Cotterell, et al., anticipate all the limitations of the rejected claims.

Claim Rejections - 35 USC § 103

16. The text of Title 35, U.S.C. § 103(a) can be found in a prior Office action.

17. Claims 47 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotterell, et al. (above) in view of the Applicant's own admission (see below).

18. Claims 47 and 48 were described previously.

19. Cotterell, et al., were described above. Briefly, this art teaches a method of administering rapamycin to patients at risk of developing sCJD, a PCD. Cotterell, et al., do not discuss administration of rapamycin analogs in general, or the particular rapamycin analogs of Claim 48. The rapamycin analogs of Claim 48 were well known at the time of filing (see instant specification, pg 7, ln 10 through pg 8, ln 1). As such, it would have been *prima facie* obvious to

one of ordinary skill in the art at the time the invention was made to administer known rapamycin analogs for the treatment of transplanted liver rejection. The patients receiving such a treatment are at risk for some PCDs, such as sCJD.

Conclusion

20. Claims 41 and 43-51 are rejected.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to PAUL ZAREK whose telephone number is (571)270-5754. The examiner can normally be reached on Monday-Thursday, 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brandon Fetterolf can be reached on (571) 272-2919. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Paul Zarek/

Examiner, Art Unit 1628